UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,717	01/30/2004	Erik J. van der Burg	1001.2706114	5133

11050 7590 12/21/2011

SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue
Suite 800
Minneapolis, MN 55403

EXAMINER	
BACHMAN, LINDSEY MICHELE	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
12/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,717	VAN DER BURG ET AL.	
	Examiner	Art Unit	
	LINDSEY BACHMAN	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 28 October 2011.

Interview Summary

Examiner spoke with Attorney Michael Reinhart on 2 December 2011 regarding the claim recitation that the deployment line is releasably attached to the implantable device. Examiner did not understand this limitation because the disclosure does not disclose how the deployment line is releasable and it appears that the deployment line is required to hold the implantable device in its expanded position. Attorney explained that a limitation stating that the deployment line is slidably attached to the implantable device is what was meant by this limitation. For the purpose of examination, Examiner will interpret "releasably attached" to mean that the deployment line is "slidably attached" to the implantable device in claims 1 and 11.

Response to Arguments

Applicant's arguments filed 28 October 2011 with respect to the rejection(s) of claim(s) 1 and 11 under Heubsch'422 in view of Kerr'896 have been fully considered and are persuasive because the retention element of Heubsch'422 is not proximal to the proximal end of the implantable device, as required by the amended claims. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gunther'942 and Bohan'539.

Claim Rejections - 35 USC § 112

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 11 recite that the deployment line is releasably attached to the implantable device. There is no disclosure in the specification of how the deployment line is released from the implantable device in the embodiment of Figure 33 and it is not clear how the deployment line could be releasably attached to the implantable device. Examiner can only visualize that the deployment line is cut to release it from the implantable device. However, typically, when two members are described in claims to be releasably attached, it means that they are releasably attached in a non-destructive manner. Clarification is required. For the purpose of examination, Examiner will interpret "releasably attached" in claims 1 and 11 to mean slidably attached, as discussed with Attorney Michael Reinhart.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunther et al. (US Patent 5,329,942).

Claim 1: Gunther'942 teaches an implantable device (11; Figures 2, 3) that is movable between a reduced cross-section (Figure 2) and an enlarged cross-section (Figure 3). When in the enlarged cross-section configuration, the device increases radially in dimension from the proximal end to the apex portion and decreases radially in dimension from the apex portion to the distal end. Gunther'942 further teaches a deployment catheter (30) with a proximal end and a distal end and lumen adapted to receive the implantable device (column 6, lines 24-46). The deployment catheter and implantable device are adapted to extend through a sheath (column 6, lines 32-34).

Gunther'942 further teaches a deployment line (15) that is adapted to extend through the deployment catheter and is slidably attached to the implantable device (column 4, lines 31-37). Gunther also teaches a retention element (19) disposed on the deployment line and capable of being fixed to the deployment line (via lock 23) to retain the implantable device in a fully deployed state.

Claim 2: The implantable device (11) is an implantable frame.

Claims 4, 5: The frame contains at least six spokes (Figures 2, 3).

Claim 6: Each spoke is movable from an axial orientation when the device is in the reduced cross-section to an inclined orientation when the implantable device is in the enlarged cross-section (Figures 2 and 3).

Claim 7: Each spoke has a proximal section, distal section and a bend in between when the implantable device is in the enlarged cross-section (Figure 3).

Claim 8: The claimed phrase "wherein the spokes are cut from a tube" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference.

Claim 10: The implantable device is movable between the reduced and enlarged cross-section when it is outside of the deployment catheter.

Claims 1 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohan et al. (US Patent 5,279,539).

Claim 1: Bohan'539 teaches a deployment system that contains an implantable device (11) that is movable between a reduced cross-section (Figure 11) and an enlarged cross-section (Figure 1). The device has a proximal end and a distal end. The device, when fully deployed (Figure 11), increases radially in dimension from the proximal end to an apex and then decreases radially in dimension from the apex to the distal end (Figure 11).

Bohan'539 further teaches a sheath (42) and a deployment catheter (13). A deployment line (31) that extends through the deployment catheter and is slidably attached to the implantable device (Figure 1, Figure 11). Bohan'539 further discloses a retention element (34) on the deployment line proximal to the implantable device to retain the implantable device in a fully deployed state (Figure 7, 11)

Claim 21: The deployment line is doubled back so there are two segments of the deployment line extending from the proximal end to the distal end (Figure 7).

Claim 22: The deployment line is looped over the proximal end and distal end (Figure 7).

Claim 23: The retention element (34) is a slip knot (column 6, line 6).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther'942, is applied to claim 1, further in view of Brooks et al. (US Patent 6,346,116).

Gunther'942 teaches the limitations of claim 3 except that the implantable device is self-expanding.

Brooks'116 teaches a similar device that contains a self-expanding implantable member (Figure 1; column 5, line 51). Self-expanding members are well known in the art. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements by known methods with no change in their respective functions, and the combination would have yielded predictable results tone of ordinary skill in the art at the time of the invention.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther'942, as applied to claim 1, further in view of Tsukernik et al. (US Patent 6,251,122).

Gunther'942 teaches the limitations of claim 9 except for the use of tissue attachment elements.

Tsukernick'122 teaches a filter device that is configured for temporary use (abstract) that contains barbs (60, 62) to hold the filter in place (column 4, lines 51-62). It would have been obvious to one of ordinary skill in the art to modify the device taught by Gunther'942 with a barb, as taught by Tsukernick'122, in order to provide the stated advantages.

Claims 11-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther'942 in view of Yadav et al. (US Patent 6,391,044)

Claim 11, 14, 18: Gunther'942 teaches an implantable device (11; Figures 2, 3) having a proximal end, distal end and a plurality of supports. The implantable device is movable between a reduced cross-section (Figure 2) and an enlarged cross-section (Figure 3). Gunther'942 further teaches a deployment catheter (30) with a proximal end and a distal end and lumen adapted to receive the implantable device (column 6, lines 24-46). The deployment catheter and implantable device are adapted to extend through a trans-septal catheter ("sheath", column 6, lines 32-34).

Gunther'942 further teaches a deployment line (15) that is adapted to extend through the deployment catheter and is slidably attached to the implantable device (column 4, lines 31-37). The implantable device is configured to move between it's

enlarged cross-section and reduced cross-section by supplying tension (proximal retraction) the deployment line (15) relative to retention element 19. Gunther'942 also teaches a retention element (19) disposed on the deployment line and capable of being fixed to the deployment line (via lock 23) to retain the implantable device in a fully deployed state.

Gunther'942 does not teach a barrier on the implantable device.

Yadav'044 teaches a barrier (20) that is a membrane on the implantable device (35) to aid in providing further filtering ability to the implantable device so that blood flow is not impeded but micro- and macro-emboli are blocked (column 3, lines 8-10). It would have been obvious to one of ordinary skill in the art to modify the device taught by Gunther'942 with a barrier, as taught by Yadav'044, in order to provide the stated advantages.

Claim 12: The implantable device has a proximal hub (18). The supports extend distally from the proximal hub.

Claim 13: When in the enlarged cross-section configuration, the implantable device increases radially in dimension from the proximal end to the apex portion and decreases radially in dimension from the apex portion to the distal end.

Claim 19, 20: The implantable device is movable between the reduced and enlarged cross-section when it is outside of the deployment catheter and the trans-septal catheter.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther'942 in view of Yadav'044, as applied to claim 14, further in view of Brooks et al. (US Patent 6,346,116).

Gunther'942 in view of Yadav'044 teach the limitations of claim 15 except for a filter membrane made of ePTFE.

Brooks'116 teaches a filter membrane expanded by a frame (Figure 1). Brooks'116 that it is known to make the filter membrane out of ePTFE (column 3, line 57 to column 4, line 6). The claim would have been obvious because the substitution for one known filter membrane material for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther'942 in view of Yadav'044, as applied to claim 11, further in view of Tsukernik'122.

Gunther'942 teaches the limitations of claims 16 and 17 except for the use of tissue attachment elements (barbs)

Tsukernick'122 teaches a filter device that is configured for temporary use (abstract) that contains barbs (60, 62) to hold the filter in place (column 4, lines 51-62). It would have been obvious to one of ordinary skill in the art to modify the device taught by Gunther'942 with a barb, as taught by Tsukernick'122, in order to provide the stated advantages.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached Monday through Thursday from 7:30am to 4:00pm and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Gary Jackson, at 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lindsey Bachman
/L. B./
Examiner, Art Unit 3734
December 16, 2011

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734